





PCI-CAMPOS ADVISORY OVERSIGHT COMMITTEE JANUARY 20TH, 2011



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Enrollment Update as of 12/31/2010

■ STEMI	164 (34.10%)
■ NSTEMI	135 (28.07%)
■ Unstable Angina	97 (20.07%)
■ Stable Angina	61 (12.86%)
■ No Sxs, no angina	23 (4.78%)
■ Sx unlikely to be ischemic	1 (0.21%)
<hr/>	
Total	481 patients

Enrollment Update as of 12/31/2010

Enrolled patients (8/1/2010 – 12/31/2010)

	Total PCIs	Primary PCIs
Pilot-Hospital 1	153	31 (20.26%)
Pilot-Hospital 2	93	30 (32.26%)
Pilot Hospital 3	73	30 (41.10%)
Pilot-Hospital 4	34	9 (26.47%)
Pilot Hospital 5	55	15 (27.27%)
Pilot-Hospital 6	73	49 (67.12%)

Enrollment Update as of 12/31/2010

Hospital 1:

■ STEMI	31 (20.26%)
■ NSTEMI	50 (32.68%)
■ Unstable Angina	36 (23.53%)
■ Stable Angina	25 (16.34%)
■ No Sxs, No Angina	11 (7.19%)
■ Sxs unlikely to be ischemic	0 (0%)
<hr/>	
■ Total	153 patients

Enrollment Update as of 12/31/2010

Hospital 2:

■ STEMI	30 (32.26%)
■ NSTEMI	21 (22.58%)
■ Unstable Angina	21 (22.58%)
■ Stable Angina	13 (13.98%)
■ No Sxs, No Angina	8 (8.60%)
■ Sxs unlikely to be ischemic	0 (0%)
<hr/>	
■ Total	93 patients

Enrollment Update as of 12/31/2010

Hospital 3:

■ STEMI	30 (41.10%)
■ NSTEMI	15 (20.55%)
■ Unstable Angina	21 (28.77%)
■ Stable Angina	6 (8.22%)
■ No Sxs, No Angina	1 (1.37%)
■ Sxs unlikely to be ischemic	0 (0%)
<hr/>	
■ Total	73 patients

Enrollment Update as of 12/31/2010

Hospital 4:

■ STEMI	9 (26.47%)
■ NSTEMI	14 (41.18%)
■ Unstable Angina	4 (11.76%)
■ Stable Angina	5 (14.71%)
■ No Sxs, No Angina	1 (2.94%)
■ Sxs unlikely to be ischemic	1 (2.94%)
<hr/>	
■ Total	34 patients

Enrollment Update as of 12/31/2010

Hospital 5:

■ STEMI	15 (27.27%)
■ NSTEMI	21 (38.18%)
■ Unstable Angina	8 (14.55%)
■ Stable Angina	8 (14.55%)
■ No Sxs, No Angina	3 (5.45%)
■ Sxs unlikely to be ischemic	0 (0%)
<hr/>	
■ Total	55 patients

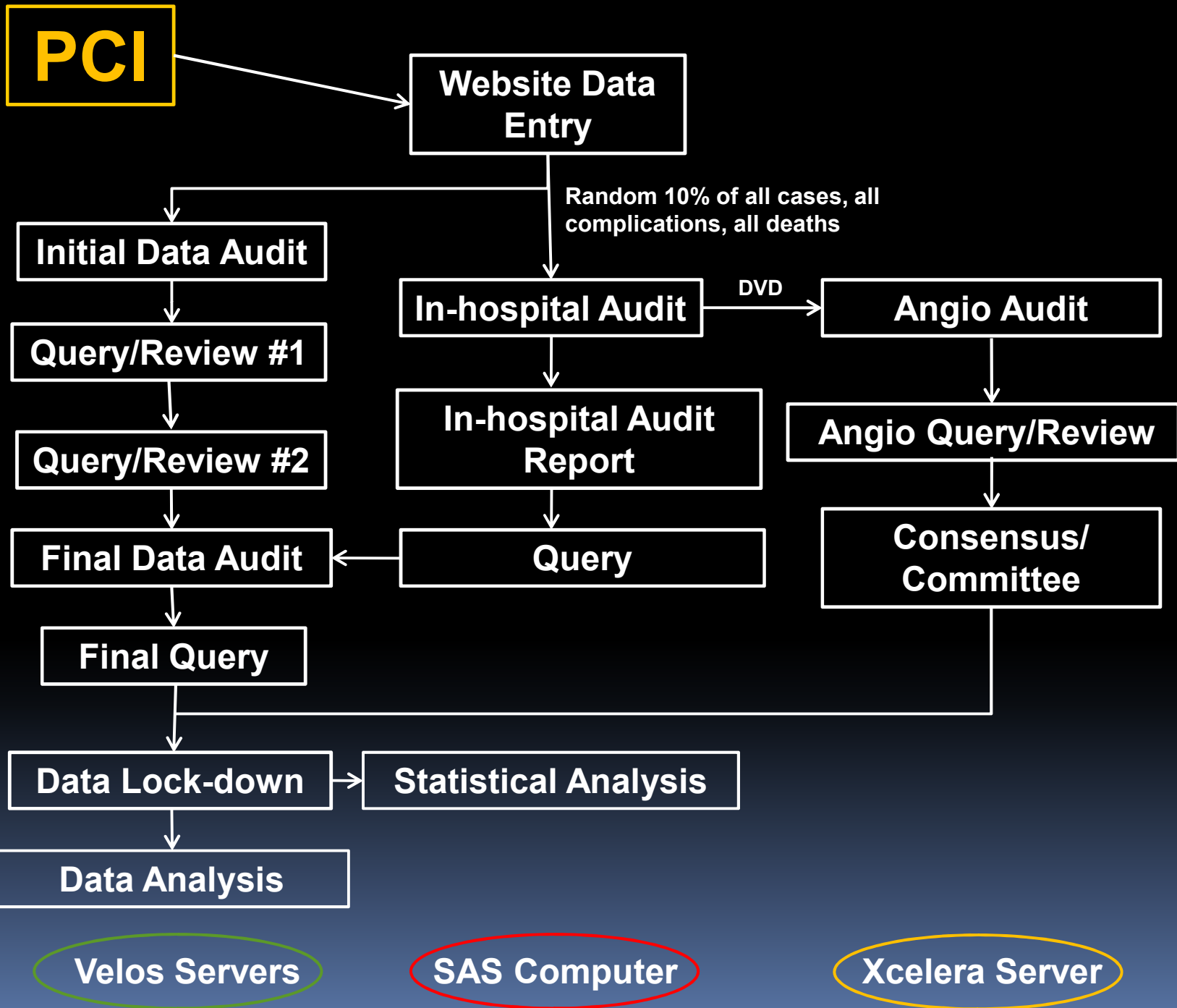
Enrollment Update as of 12/31/2010

Hospital 6:

■ STEMI	49 (67.12%)
■ NSTEMI	13 (17.81%)
■ Unstable Angina	7 (9.59%)
■ Stable Angina	4 (5.48%)
■ No Sxs, No Angina	0 (0%)
■ Sxs unlikely to be ischemic	0 (0%)
<hr/>	
■ Total	73 patients

Software Update

- Procedure medications did not populate: resolved in December 2010
- Data lock-down feature: enabled December 2010
- Intermittent log-on block: resolved with additional load balance patch in January 2011
- Lesion counter vs. associated lesion: resolved in January 2011
- Definition pop-up: resolved in January 2011
- Automatic log-out warning: available in February 2011



Initial Data Audit

- Completeness check
- Internal consistency (arrival date/procedure date, CHF, troponin/MI, PCI-status, CABG/graft, CTO/STEMI, appropriate meds)
- NCDR definitions compliance

Initial Data Audit: Example

- CAD presentation

The screenshot shows a medical form titled "D. Cath Lab Visit" with the instruction "(COMPLETE FOR EACH CATH LAB VISIT)". The form is for "CLINICAL EVALUATION LEADING TO THE PROCEDURE". A red circle highlights the "Unstable angina" dropdown menu in the "CAD Presentation" section. Other sections include "IF STEMI or Non-STEMI, Symptom Onset Date/Time", "Time Estimated", "Time Not Available", "Anginal Classification w/in 2 Weeks", "Arm-Anginal Medication w/in 2 weeks", "Beta Blockers", "Calcium Channel Blockers", "Long Acting Nitrates", "Ranolazine", "Other", "Heart Failure w/in 2 Weeks", "If Yes, NYHA Class w/in 2 weeks", "Cardiomyopathy or LV Systolic Dysfunction", "Pre-operative Evaluation Before Non-Cardiac Surgery", "Cardiogenic Shock w/in 24 Hours", and "Cardiac Arrest w/in 24 Hours".

CAD presentation has to be consistent with pre-procedure troponin levels and has to be documented by a physician in the records

Initial Data Audit: Example

- Cardiomyopathy or LV systolic dysfunction

The screenshot shows a clinical evaluation form titled 'D. Cath Lab Visit (COMPLETE FOR EACH CATH LAB VISIT)'. It includes sections for 'CLINICAL EVALUATION LEADING TO THE PROCEDURE', 'Cath Presentation', 'Symptom Onset Date/Time', 'Time Estimated', 'Time Not Available', 'Unstable angina', 'CCS II', 'Anginal Classification w/in 2 Weeks', 'Anti-Anginal Medication w/in 2 Weeks', 'Beta Blockers', 'Calcium Channel Blockers', 'Long Acting Nitrate', 'Ranolazine', 'Other', 'Heart Failure w/in 2 Weeks', 'NYHA Class w/in 2 Weeks', 'Cardiomyopathy or LV Systolic Dysfunction', 'Pre-operative Evaluation Before Surgery', 'Cardiogenic Shock w/in 24 Hours', and 'Cardiac Arrest w/in 24 Hours'. The field 'Cardiomyopathy or LV Systolic Dysfunction' is highlighted with a red circle and set to 'Yes'.

Cardiomyopathy or LV systolic dysfunction has to be coded 'yes' if the INDICATION for the cath was the assessment of cardiomyopathy or LV systolic dysfunction.

Initial Data Audit: Example

■ Best Estimate of Coronary Anatomy

F. Best Estimate of Coronary Anatomy (Complete For Each Cath Lab Visit)

Dominance [6100](#) Right

Coronary Territory	Native Artery Percent Stenosis in >=2mm vessels	Grafts Supplying Coronary Territory (note 1) Percent Stenosis
Left Main	<input type="text" value="0"/> % 6110 Not Available 6111 No <input type="text"/>	
Proximal LAD	<input type="text" value="0"/> % 6120 Not Available 6121 No <input type="text"/>	<input type="text"/> % 6170 Not Available 6171 No <input type="text"/>
Mid/Distal LAD, Diag Branches	<input type="text" value="98"/> % 6130 Not Available 6131 No <input type="text"/>	<input type="text"/> % 6180 Not Available 6181 No <input type="text"/>
CIRC, OMs, LPDA, LPL Branches	<input type="text" value="0"/> % 6140 Not Available 6141 No <input type="text"/>	<input type="text"/> % 6190 Not Available 6191 No <input type="text"/>
RCA, RPDA, RPL, AM Branches	<input type="text" value="20"/> % 6150 Not Available 6151 No <input type="text"/>	<input type="text"/> % 6200 Not Available 6201 No <input type="text"/>
Ramus	<input type="text" value=""/> % 6160 Not Available 6161 Yes <input type="text"/>	<input type="text"/> % 6210 Not Available 6211 No <input type="text"/>

The degree of stenosis of EACH coronary vessel has to be dictated in the cath report. Coders cannot interpret terms such as 'moderate stenosis'. 0% should only be entered if the vessel is free of CAD and not if the percentage of stenosis is unavailable.

Initial Data Audit: Example

- PCI-status: elective, urgent, emergent, or salvage has to be consistent with CAD presentation

Selection Text	Definition
Elective	The procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. <u>For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge. If the diagnostic catheterization was elective and there were no complications, the PCI would also be elective.</u>
Urgent	<u>The procedure should be performed on an inpatient basis and prior to discharge because of significant concerns that there is risk of ischemia, infarction and/or death. Patients who are outpatients or in the emergency department at the time that the cardiac catheterization is requested would warrant an admission based on their clinical presentation.</u>
Emergency	The procedure should be performed as soon as possible because of substantial concerns that ongoing ischemia and/or infarction could lead to death. <u>"As soon as possible" refers to a patient who is of sufficient acuity that you would cancel a scheduled case to perform this procedure immediately in the next available room during business hours, or you would activate the on-call team were this to occur during off-hours.</u>
Salvage	<u>The procedure is a last resort. The patient is in cardiogenic shock when the PCI begins (i.e. at the time of introduction into a coronary artery or bypass graft of the first guidewire or intracoronary device for the purpose of mechanical revascularization). Within the last ten minutes prior to the start of the case or during the diagnostic portion of the case, the patient has also received chest compressions for a total of at least sixty seconds or has been on unanticipated extracorporeal circulatory support (e.g. extracorporeal mechanical oxygenation, or cardiopulmonary support).</u>

Initial Data Audit: Queries

Work in progress	Complete	both forms filled out	CAD presentation	
	✓	✓	STEMI	ok
✓		✓	elective PCI	preoperative evaluation before non cardiac surgery? (5055)
✓		✓	NSTEMI	compare 6040 and 7020, 7035 - please double check
	✓	✓	unstable angina	unstable angina, but troponin 1.36 - please check
	✓	✓	NSTEMI	NSTEMI, but Troponin 0.005 - please check; discharge meds no BB (contraindication?)
	✓	✓	STEMI	is field 5050 correct (reason for cath)?, fill out fields 7040,7045,7046, and 7240,7235, if available
	✓	✓	unstable angina	5202 (state if data unavailable), fill out 7110
	✓	✓	unstable angina	check if 5305 is really 'yes' since no device was deployed (no intracoronary devices are listed)
	✓	✓	unstable angina	fill out field 4045 if pat. had prior CABG; fill out 7110
	✓	✓	unstable angina	troponin 0.16 with UA please check, field 5050? - code only 'yes' if
	✓	✓	unstable angina	cardiomyopathy was indication for cath
	✓	✓	STEMI	fill out 7040,7045,7046; 7120
	✓	✓	unstable angina	fill out 7110
	✓	✓	STEMI	ok
	✓	✓	STEMI	fill out 4045
	✓	✓	unstable angina	lesion 3 field 7220 should be yes; fill out 7110
	✓	✓	unstable angina	ok
	✓	✓	no sxs, no angina	ok
	✓	✓	unstable angina	CIRC is listed as 80% stenosis, CIRC PCI is 90% - please check, Trop 0.05 (unstable angina)
✓		✓	STEMI	IABP during PCI , otherwise ok, Troponin I 0.06 (STEMI)
	✓	✓	unstable angina	Troponin 0.95 (unstable angina) , normal creatinine - please check; otherwise ok
	✓	✓	unstable angina	please fill out 4055 and 4060, Trop 0.11 (unstable angina)
✓		✓	unstable angina	ok
	✓	✓	STEMI	ok
	✓	✓	stable angina	ok
	✓	✓	NSTEMI	ok
	✓	✓	unstable angina	ok

Number of query items or Missing Data Per Record after initial data audit per hospital:

0.4 items per case file

0.9 items per case file

0.7 items per case file

0.9 items per case file

1.1 items per case file

1.1 items per case file

In-Hospital Audits

66 audits at pilot-hospitals

- Hospital 1: 19 procedures audited
- Hospital 2: 15 procedures audited
- Hospital 3: 9 procedures audited
- Hospital 4: 4 procedures audited
- Hospital 5: 4 procedures audited
- Hospital 6: 15 procedures audited

In-Hospital Audits: Example

In-hospital audit report

- 4005: should be coded as “yes”; corrected now by Coder
- 5000, 7035, 7040, 7050, 7055, 7065: should be coded as STEMI per info in chart; now corrected by Coder.
- 5020: was coded as no pain but report shows 10/10 pain at rest; now corrected by Coder to CCS IV
- 9500, 9510: chart lists Aspirin given but was not coded; now corrected by Coder
- 7115, 7185, 7190, 7210: data not found in chart; interventionalist notified and addendum provided with data--? **Now corrected by coder?**
- 7195: codes as “yes” but chart data reflects “no thrombus”; now corrected by Coder
- 7250: coded as “yes” but data suggests “no”; now corrected by Coder
- 7300, 7345: coded values incorrect; corrected now by Coder
- 8005: cardiogenic shock at start of cath visit required placement of IABP & amiodorone infusion immediately post diagnostic cath and prior to PCI; completed PCI

Angiographic Audit: Diagnostic

- IABP or other mechanical ventricular support
- Diagnostic cath (and/or left heart cath) done
- Diagnostic cath status (elective, urgent, emergent, salvage)
- Coronary anatomy: % stenosis in ≥ 2 mm vessels and grafts
 - LM
 - Prox. LAD
 - Mid/Distal LAD, diag. branches
 - CIRC, OMs, LPDA, LPL branches
 - RCA, RPDA, RPL, AM branches
 - Ramus

Angiographic Audit: PCI

- Segment number of PCI coronary artery
- Culprit Lesion,
- Stenosis immediately prior to RX
 - If 100%: CTO
 - If 40-70%: IVUS
 - If 40-70%: FFR
 - If Yes: Ratio
- Pre-procedure TIMI Flow
- Prev. treated lesion
- Lesion in graft
- Lesion complexity
- Lesion length
- Thrombus present

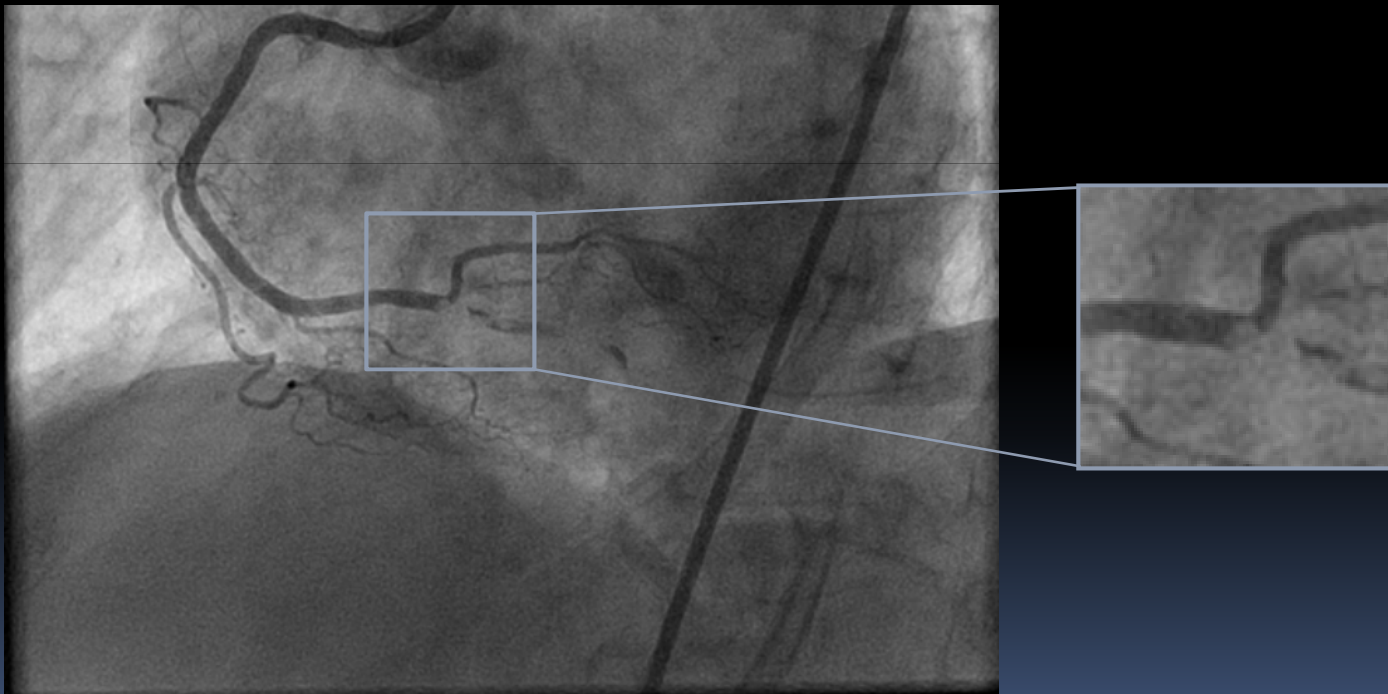
Angiographic Audit: PCI

- Bifurcation lesion
- Guidewire across lesion
- Stenosis post-procedure
- Post-procedure TIMI flow
- Device deployed
- Intracoronary devices used
- PCI complication: Significant dissection or perforation
- LVEF (if documented)

Angiographic Audit: Example 1

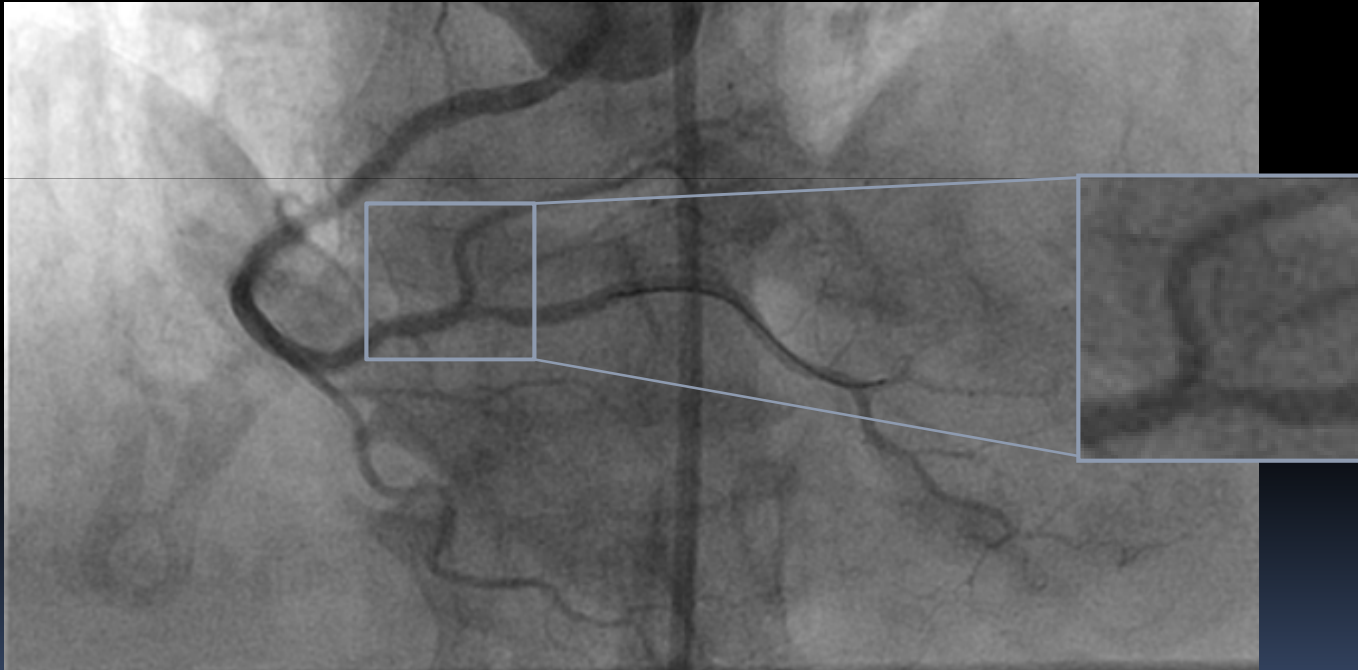
Pre-PCI:

STEMI, pre-procedure stenosis of dist. RCA 99%



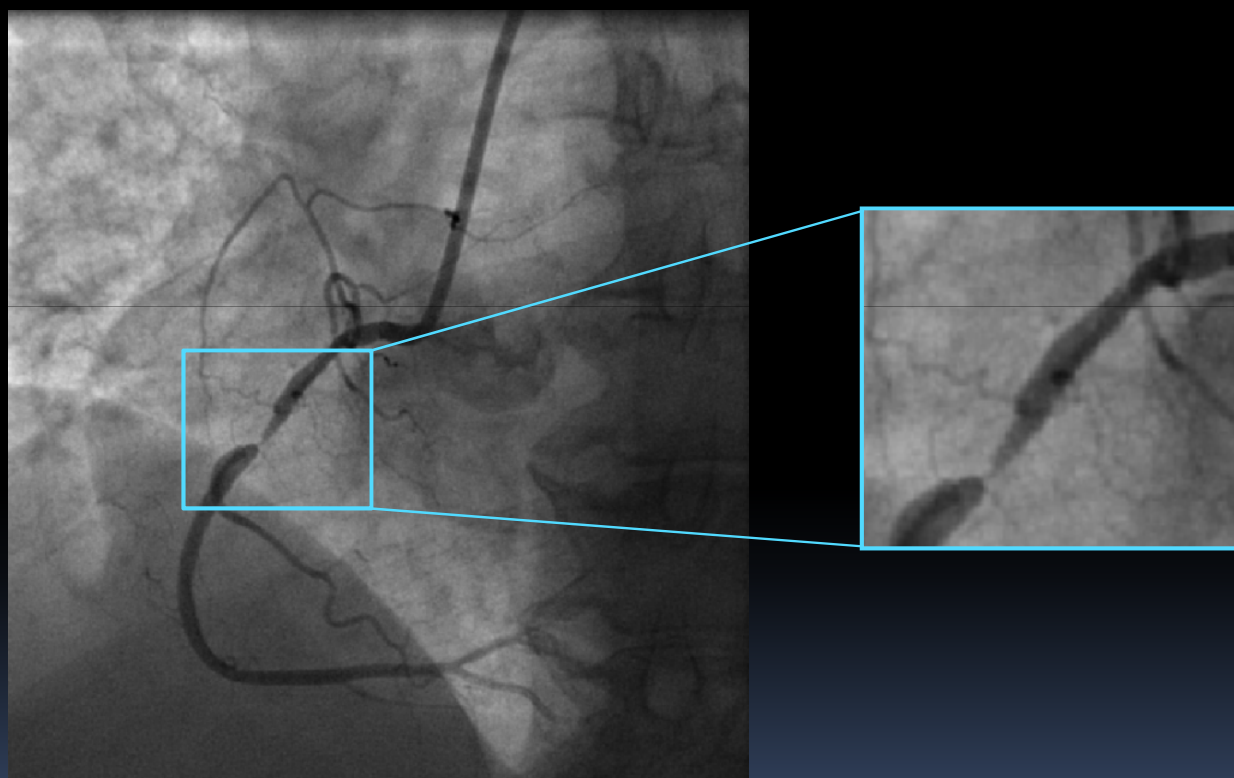
Angiographic Audit: Example 1

**Post-PCI:
POBA was performed, post-procedure stenosis
coded as 10%**



Angiographic Audit: Example 2

Pre-PCI:



Angiographic Audit: Example 2

Post-Procedure:



High Risk Patient I

(expected clinical risk in case of occlusion or other serious complication caused by the PCI)

Includes but is not limited to:

- Decompensated CHF (Killip class 3) without evidence for active ischemia
- Recent cerebrovascular attack
- Advanced malignancy
- Known clotting disorders
- LVEF \leq 25%

High Risk Patient II

(expected clinical risk in case of occlusion or other serious complication caused by the PCI)

- Left main stenosis $\geq 50\%$ or three-vessel disease ($> 70\%$ in all prox. vessels) } Unprotected by prior CABG
- Single target lesion that jeopardizes over 50% of remaining viable myocardium

High Lesion Risk I

(probability that the procedure will cause acute vessel occlusion or other serious complication)

"High lesion risk" may include, but is not limited to lesions in open vessels with the following:

- Diffuse disease (> 2 cm in length) and excessive tortuosity of prox. segments
- More than moderate calcification of a stenosis or proximal segments
- Location in an extremely angulated segment (>90°)

High Lesion Risk II

(probability that the procedure will cause acute vessel occlusion or other serious complication)

- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Other features that may, in the interventionalist's judgment, impede stent deployment

Eligible patients for elective PCI I

- High risk patient with high risk lesion should NOT be included in the pilot program
- High risk patient with a NOT high risk lesion may be included in the pilot program upon confirmation that a cardiac surgeon and an operating room are immediately available if necessary

Eligible patients for elective PCI II

- NOT high-risk patient with a high-risk lesion may be included in the pilot-program
- NOT high-risk patient with a NOT high risk lesion may be included in the pilot program

PCI Success Rate

Post procedure stenosis <20%: 93.9%
Post-procedure TIMI 3 flow: 96.6%

Field Name	Basic Stats	Count/Percentage
Stenosis Post-Procedure	Min:0.0 Max:100.0 Median:0.0 Avg:2.91	10: 15 (2.53%) 20: 13 (2.2%) 30: 8 (1.35%) 40: 1 (0.17%) 95: 2 (0.34%) 50: 2 (0.34%) 60: 2 (0.34%) 9: 1 (0.17%) 70: 4 (0.68%) 8: 1 (0.17%) 5: 3 (0.51%) 15: 1 (0.17%) 3: 1 (0.17%) 25: 1 (0.17%) 12: 1 (0.17%) 100: 2 (0.34%) 0: 533 (90.03%) 55: 1 (0.17%)
Guidewire Across Lesion	N/A	Yes: 592 (99.66%) No: 2 (0.34%)
Lesion Complexity	N/A	High/C Lesion: 206 (34.8%) Non-High/Non-C Lesion: 386 (65.2%)
Pre-Procedure TIMI Flow	N/A	TIMI - 1: 49 (8.29%) TIMI - 0: 140 (23.69%) TIMI - 3: 301 (50.93%) TIMI - 2: 101 (17.09%)
Stenosis Immediately Prior to Rx	Min:0.0 Max:100.0 Median:95.0 Avg:90.44	20: 1 (0.17%) 70: 45 (7.59%) 0: 2 (0.34%) 85: 19 (3.2%) 90: 112 (18.89%) 60: 11 (1.85%) 100: 140 (23.61%) 99: 96 (16.19%) 98: 9 (1.52%) 75: 12 (2.02%) 80: 61 (10.29%) 97: 1 (0.17%) 50: 3 (0.51%) 95: 81 (13.66%)
PCI Status	N/A	Emergency: 164 (36.61%) Elective: 140 (31.25%) Salvage: 1 (0.22%) Urgent: 143 (31.92%)
Post-Procedure TIMI Flow	N/A	TIMI - 0: 4 (0.68%) TIMI - 3: 572 (96.62%) TIMI - 2: 16 (2.7%)

PCI CAMPOS: Initial Statistics

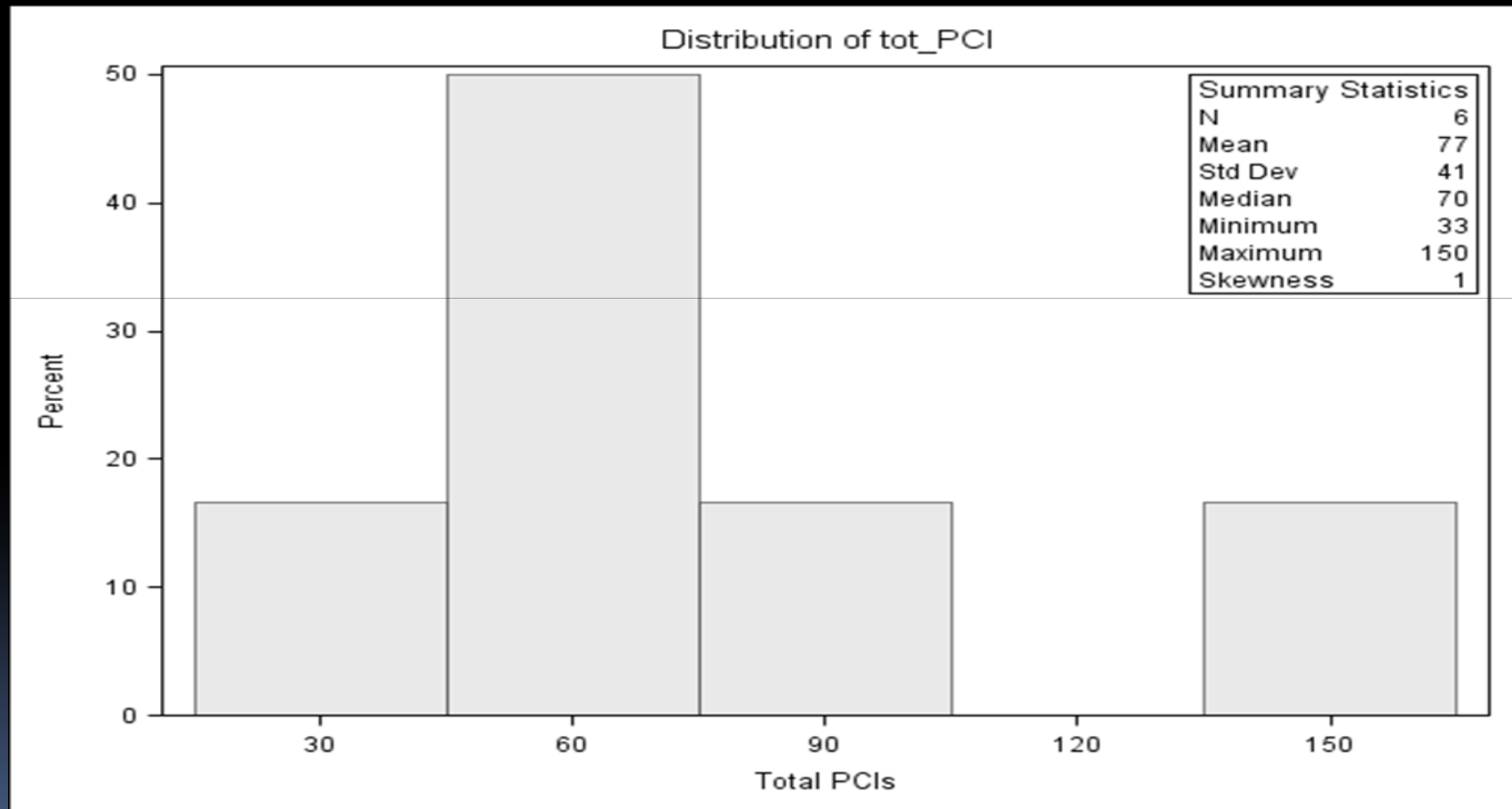
- Total submission: 481
- Complete Data Entry: N=463
- Work in Progress Data Entry: N=18

Complete Data Entry:

- In-hospital mortality: N=9, 1.94%
- Hospital observed mortality range:
0.0-8.70%

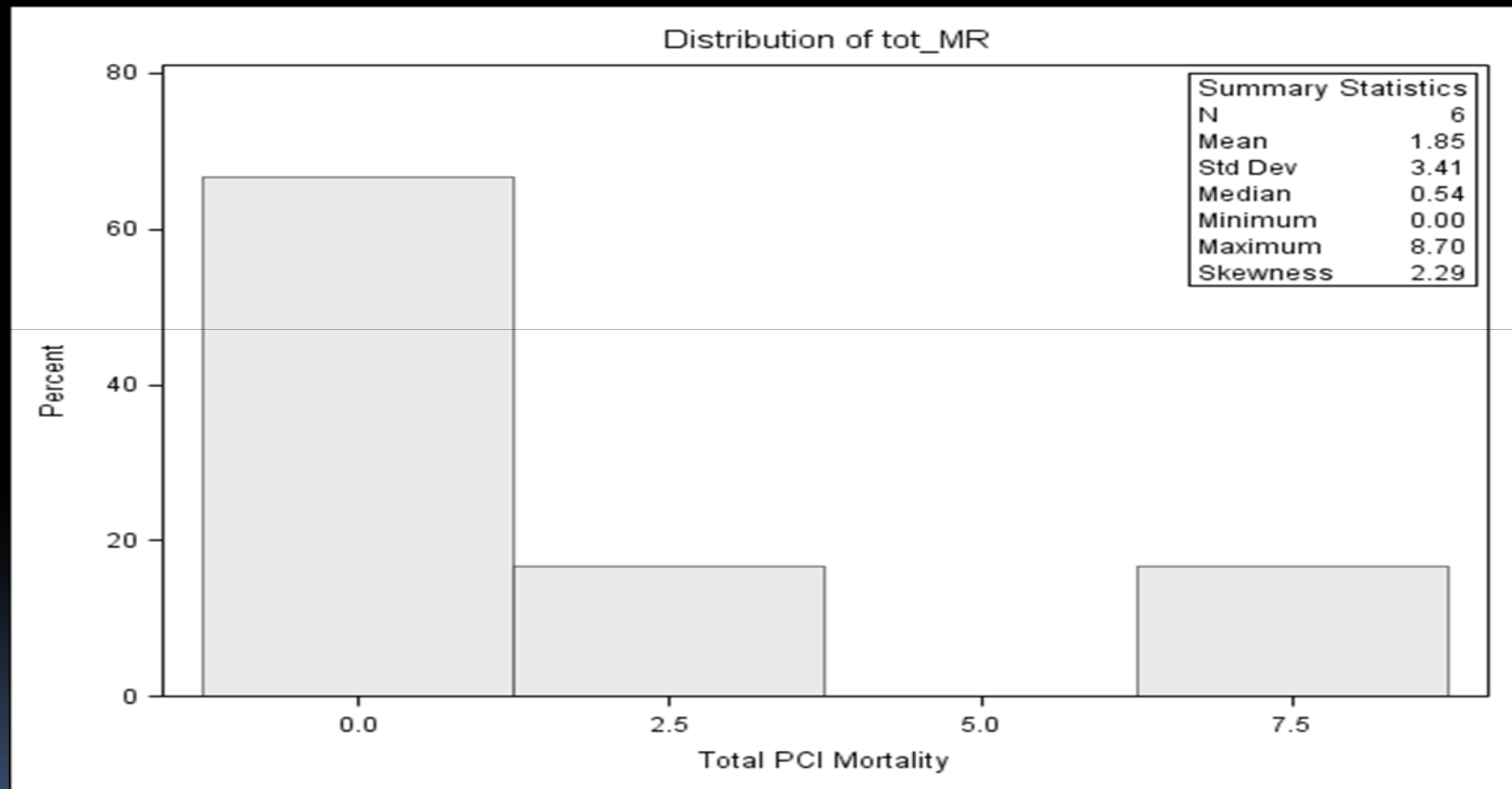
PCI CAMPOS:

Hospital Distribution of PCI Volume

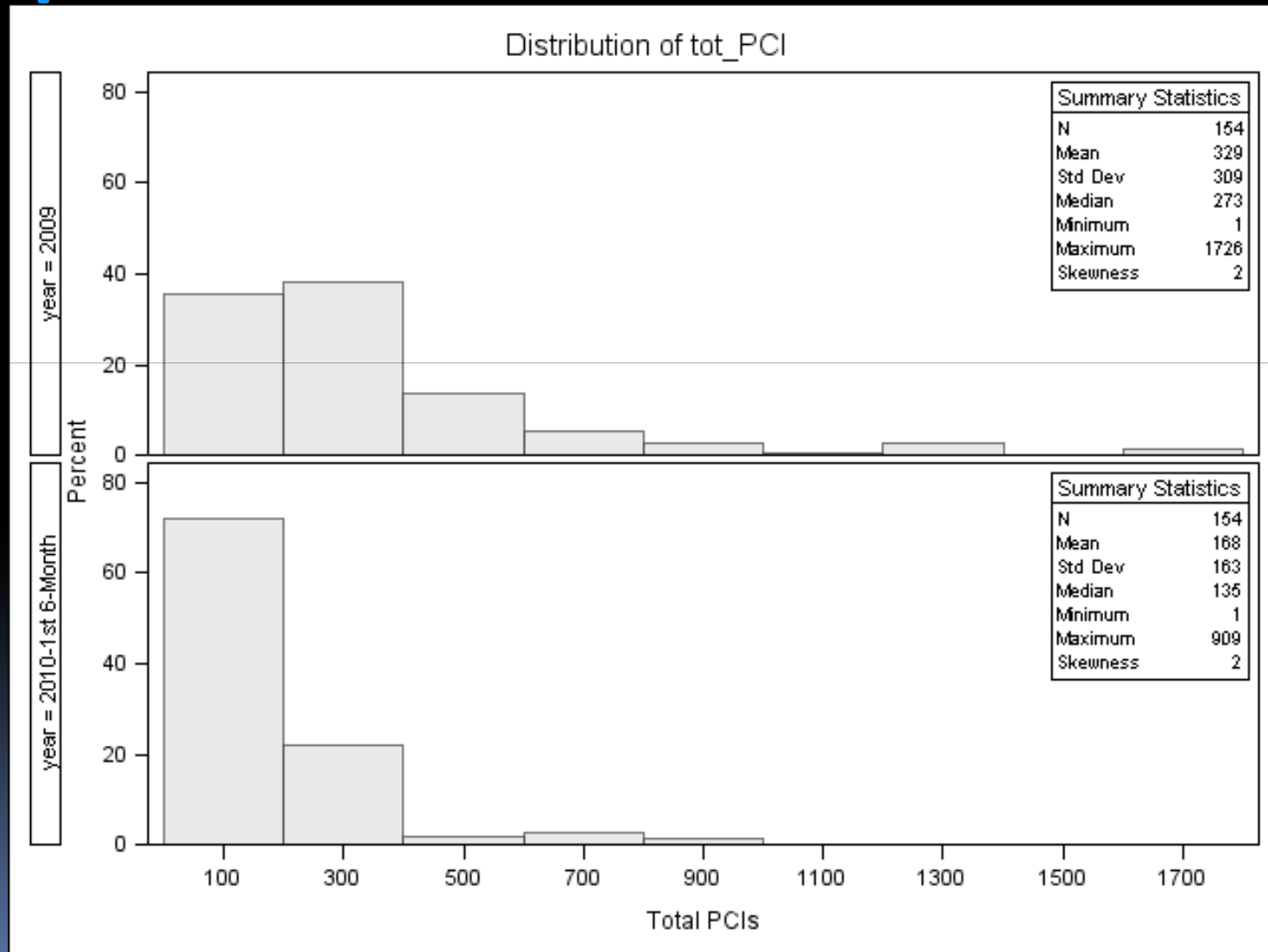


PCI CAMPOS:

Hospital Observed Mortality Rate

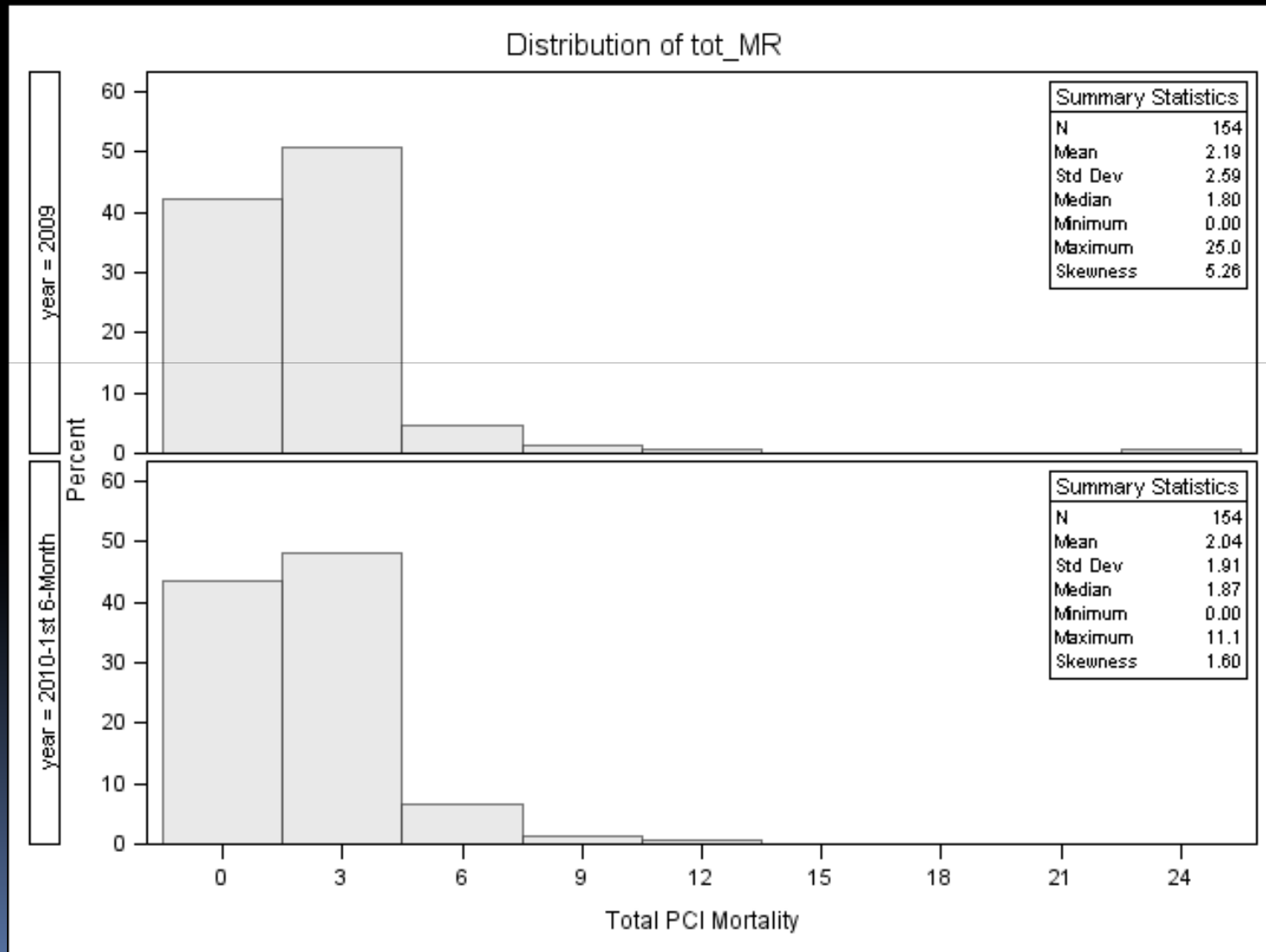


Patient Discharge Data (PDD Non-Pilot): Hospital PCI Volume



PDD Non-Pilot :

Hospital Observed Mortality Rate



PCI CAMPOS:

Complete Data Entry by MI Type

	Alive	Deceased	Total	p-value
STEMI	152	5	157	0.0554
	96.82%	3.18%	33.91%	
NSTEMI	123	4	127	
	96.85%	3.15%	27.43%	
Others	179	0	179	
	100%	0%	38.66%	
Total	454	9	463	
	98.06%	1.94%	100%	

PDD Non-Pilot vs PCI CAMPOS : Hospital Observed Mortality by MI Type

	STEMI MR% (95%CI)	NSTEMI MR% (95%CI)	No MI MR% (95%CI)	Total PCI MR% (95%CI)
PDD Non-Pilot (1/1 – 6/30/2010)	4.30 (3.59-5.01)	1.90 (1.45-2.35)	0.90 (0.55-1.24)	2.04 (1.74-2.35)
PCI-CAMPOS (8/1 – 12/31/2010)	1.99 (0-5.64)	4.16 (0-11.63)	0	1.85 (0-5.43)
P-value	0.2115	0.4724	<0.0001	0.8970




Risk adjustment

- PCI CAMPOS data as of 12/31/2010
- Risk factors:
 - Demographics
 - Prior PCI clinical conditions
 - Prior PCI lesion risk




Risk Factor Prevalence and Mortality I

Risk factor		N	Prevalence (%)	Mortality rate (%)	p-value
Age group	≤70	297	64.15	1.35	0.2133
	>70	166	35.85	3.01	
Gender	Female	148	31.97	2.03	0.9292
	Male	315	68.03	1.90	
White	No	101	21.81	2.97	0.3981
	Yes	362	78.19	1.66	
Body Mass Index	18.5-39.9	433	93.52	2.08	0.7276
	< 18.5	7	1.51	0.00	
	40.0+	23	4.97	0.00	

Risk Factor Prevalence and Mortality II

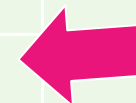
	Risk factor	N	Prevalence (%)	Mortality rate (%)	p-value
PCI status	Elective/Urgent	291	62.85	0.69	0.0109
	Emergent/Salvage	172	37.15	4.07	
STEMI	STEMI	157	33.91	3.18	0.0554
	NSTEMI	127	27.43	3.15	
	Others	179	38.66	0.00	
Glomerular filtration rate (GFR)	Stage 1-2	410	88.55	1.46	0.0373
	Stage 3,4,5	53	11.45	5.66	
Cardiogenic shock	No	450	97.19	1.33	<.0001
	Yes	13	2.81	23.08	

Risk Factor Prevalence and Mortality III

Risk factor		N	Prevalence (%)	Mortality rate (%)	p-value
NYHA	Class I, II, III	449	96.98	1.56	0.0007
	Class IV	14	3.02	14.29	
Heart failure	No	418	90.28	1.44	0.0157
	Yes	45	9.72	6.67	
Diabetes	No diabetes	310	66.95	0.32	 0.0008
	Noninsulin diabetes	96	20.73	6.25	
	Insulin diabetes	57	12.31	3.51	
Prior PCI	No	337	72.79	2.37	0.273
	Yes	126	27.21	0.79	

Risk Factor Prevalence and Mortality IV

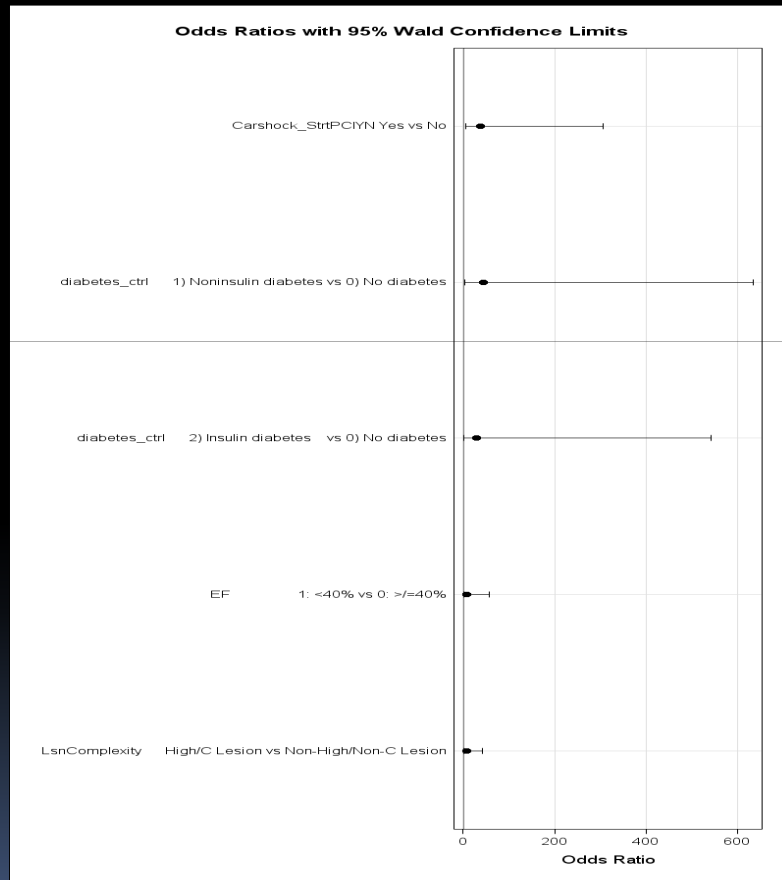
Risk factor		N	Prevalence (%)	Mortality rate (%)	p-value
Cerebrovascular Disease	No	424	91.58	1.65	0.1323
	Yes	39	8.42	5.13	
Peripheral Artery Disease	No	428	92.44	2.01	0.3863
	Yes	35	7.56	0.00	
Cronic Lung Disease	No	413	89.20	1.69	0.2648
	Yes	50	10.80	4.00	
Intra-aortic balloon pump	No	448	96.76	1.34	<.0001
	Yes	15	3.24	20.00	



Risk Factor Prevalence and Mortality V

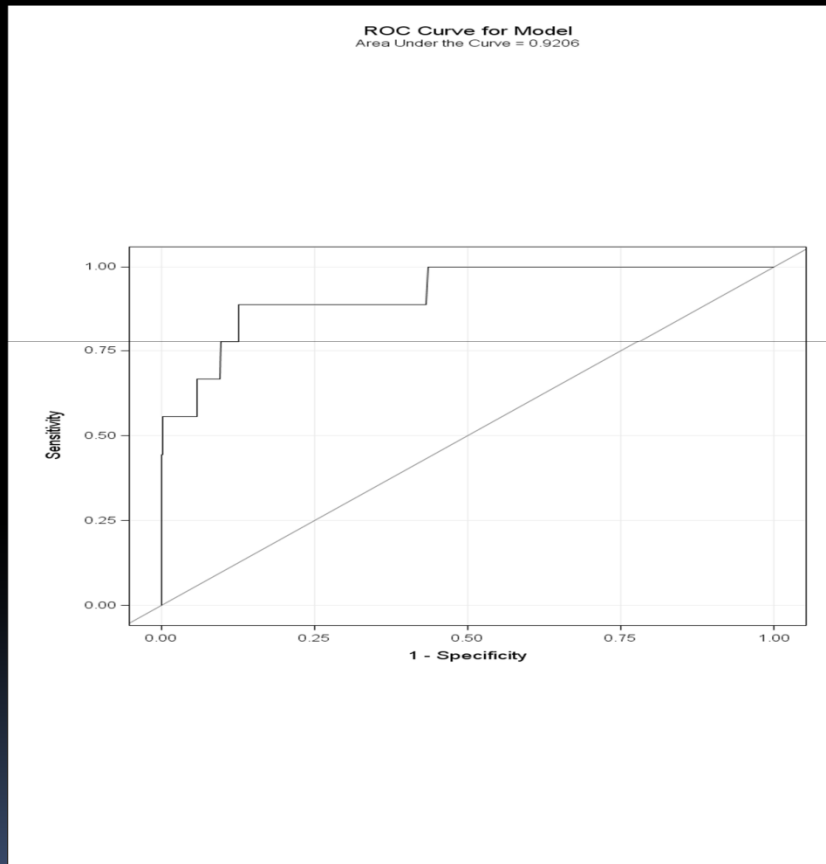
Risk factor		N	Prevalence (%)	Mortality rate (%)	p-value
Left main stenosis	≤75%	449	96.98	2.00	0.5927
	>75%	14	3.02	0.00	
Ejection Fraction	≥40%	443	95.68	1.58	0.0076
	<40%	20	4.32	10.00	
Lesion complexity	High/C Lesion	189	40.82	3.70	0.0227
	Non-High/Non-C Lesion	274	59.18	0.73	
Thrombosis	No	311	67.17	1.61	0.4536
	Yes	152	32.83	2.63	
Preproc TIMI	Other	323	69.76	0.93	0.0163
	TIMI - o	140	30.24	4.29	

PCI-CAMPOS : Multivariable Logistic Regression Model for In-hospital Mortality I



- 21 risk factors
- 5 sig. predictors via stepwise selection ($\alpha < 0.05$)
- Adjusted OR > 2.00:
 - Cardiogenic shock
 - Diabetes
 - Ejection Fraction < 40%
 - Lesion complexity: High/C

PCI-CAMPOS : Multivariable Logistic Regression Model for In-hospital Mortality II



- Parsimonious Model:
 - C-statistic: 0.873
 - Hosmer-Lemeshow test: $p < 0.0001$
- Full model:
 - C-statistic: 0.921
 - HL test: $p = 0.3985$

PCI CAMPOS:

Initial risk-adjusted PCI in-hospital mortality

Hospital	PCI Cases	Death at Discharge	Observed Mortality Rate (%)	Expected Mortality Rate (%)	Risk-Adjusted Mortality Rate (% , RAMR)	95%CI for RAMR	Performance Rating
PCI-CAMPOS	463	9	1.94				
Pilot-hospital #1	150	2	1.33	1.16	2.23	(0.27, 8.05)	Not Different
Pilot-hospital #2	93	1	1.08	1.5	1.39	(0.04, 7.75)	Not Different
Pilot-hospital #3	71	0	0	1.12	0	(0.00, 9.03)	Not Different
Pilot-hospital #4	33	0	0	1.09	0	(0.00, 19.82)	Not Different
Pilot-hospital #5	47	0	0	1.03	0	(0.00, 14.85)	Not Different
Pilot-hospital #6	69	6	8.70	6.13	2.76	(1.01, 5.99)	Not Different

Statistical Analysis Summary

- PCI-CAMPOS vs PDD Non-Pilot observed hospital mortality:
No significant difference
- PCI-CAMPOS risk-adjusted mortality:
No significant outlier hospitals

Patients Transferred for Cardiac Surgery

	<i>emergent</i>	<i>urgent</i>	<i>elective</i>	<i>Total</i>	<i>Deaths</i>
<i>Pilot-Hospital #1</i>	1	0	0	1	0
<i>Pilot-Hospital #2</i>	0	0	1	1	0
<i>Pilot-Hospital #3</i>	0	0	1	1	0
<i>Pilot-Hospital #4</i>	0	1	0	1	0
<i>Pilot-Hospital #5</i>	0	1	0	1	0
<i>Pilot-Hospital #6</i>	1	2	0	3	1
<i>Total</i>	2	4	2	8	1

Patients Transferred for Cardiac Surgery

	Date transfer	Time of decision for transfer	Time of arrival at CABG facility	Arrival at the OR
NSTEMI; transfer for urgent but not emergent CABG; PCI failure without clinical deterioration		17:50	19:23	13:00 two days later
STEMI; transfer for urgent aortic valve replacement; CABG was elective; 2nd form was not filled out				
STEMI; transfer due to PCI-dissection, patient was to be stabilized at CABG facility before surgery, but died before surgery		19:44	22:15	no CABG
STEMI; transfer for CABG due to failed PCI (RCA was still 70% after PCI); but received another PCI at CABG facility and no CABG		4:18	6:18	13:03 (PCI, not CABG)
STEMI, urgent transfer for CABG due to failed PCI, but surgeons decided against CABG and treated patient medically, no CABG done		6:54	8:43	no CABG
STEMI; patient was transferred for elective CABG, 2nd form was not filled out				
STEMI; RCA stented, planned CABG (high degree LM, LAD, CIRC stenoses); surgeon saw patient on the day after the PCI and recommended transfer for CABG; patient received CABG two days later.		12:39 (day after PCI)	14:30 (day after PCI)	8:09 two days later
NSTEMI; transferred for emergent CABG		11:55	13:29	13:41

PCI-CAMPOS Summary I

- **Initial Enrollment:** 481 patients/5 mos
164 STEMIs
- **Data Completion:** 463 website entries
- **Audit queries:** 0.4-1.1 items/record
- **Audit Completions:** 66 in-hospital audits
66 angio audits
- **Data Set Eligibility:** 463 patients
- **Emergency Transfer Time:** 2:31 hours
1:34 hours

PCI-CAMPOS Summary II

- **PCI success rate:** 93.9% (<20% stenosis)
96.6% (TIMI 3)
- **Observed mortality:** 1.94% (0 – 8.70%)
- **Transfers:** Emergent 0.43%
Urgent 0.86%
Elective 0.43%
- **Risk factor modeling:** PCI-status, GFR, cardiogenic shock, NYHA, CHF, DM, IABP, EF, lesion complexity, pre-procedure TIMI
- **Hospital risk-adjusted mortality:** 0 – 2.76%

NCDR PCI on-site surgery data

Option 1: ACCF NCDR to create and transmit a de-identified dataset of CA hospitals that does not require hospital consents, with select elements suppressed, masked, or calculated, including 3 transmissions of patient data from discharges between 7/1/09-6/30/11: \$105,000

Option 2: ACCF NCDR to create and transmit a patient record dataset of CA hospitals that does require hospital consents, including 3 transmissions of patient data from discharges between 7/1/09-6/30/11: \$26,000

Option 3: ACCF NCDR to release technical documents with updates to unlock files data files (both XML and CSV formats) sent directly from CA hospitals to UC Davis (or subcontractor), no technical or project consultation time included but full access to www.NCDR.com: \$1,000 per year

Appropriateness Criteria for PCI

Table 1. Patients With Acute Coronary Syndromes

Indication	Appropriateness Score (1–9)
1. <ul style="list-style-type: none"> • STEMI • Less than or equal to 12 hours from onset of symptoms • Revascularization of the culprit artery 	A ₍₉₎ *
2. <ul style="list-style-type: none"> • STEMI • Onset of symptoms within the prior 12 to 24 hours • Severe HF, persistent ischemic symptoms, or hemodynamic or electrical instability present 	A ₍₉₎
3. <ul style="list-style-type: none"> • STEMI • Greater than 12 hours from symptom onset • Asymptomatic; no hemodynamic instability and no electrical instability 	I ₍₃₎
4. <ul style="list-style-type: none"> • STEMI with presumed successful treatment with fibrinolysis • Evidence of HF, recurrent ischemia, or unstable ventricular arrhythmias present • One-vessel CAD, presumed to be the culprit artery 	A ₍₉₎
5. <ul style="list-style-type: none"> • STEMI with presumed successful treatment with fibrinolysis • Asymptomatic; no HF or no recurrent ischemic symptoms, or no unstable ventricular arrhythmias • Normal LVEF • One-vessel CAD presumed to be the culprit artery 	U ₍₅₎
6. <ul style="list-style-type: none"> • STEMI with presumed successful treatment with fibrinolysis • Asymptomatic; no HF, no recurrent ischemic symptoms, or no unstable ventricular arrhythmias at time of presentation • Depressed LVEF • Three-vessel CAD • Elective/semi-elective revascularization 	A ₍₈₎
7. <ul style="list-style-type: none"> • STEMI with successful treatment of the culprit artery by primary PCI or fibrinolysis • Asymptomatic; no HF, no evidence of recurrent or provokable ischemia or no unstable ventricular arrhythmias during index hospitalization • Normal LVEF • Revascularization of a non-infarct related artery during index hospitalization 	I ₍₂₎
8. <ul style="list-style-type: none"> • STEMI or NSTEMI and successful PCI of culprit artery during index hospitalization • Symptoms of recurrent myocardial ischemia and/or high-risk findings on noninvasive stress testing performed after index hospitalization • Revascularization of 1 or more additional coronary arteries 	A ₍₈₎
9. <ul style="list-style-type: none"> • UA/NSTEMI and high-risk features for short-term risk of death or nonfatal MI • Revascularization of the presumed culprit artery 	A ₍₉₎
10. <ul style="list-style-type: none"> • UA/NSTEMI and high-risk features for short-term risk of death or nonfatal MI • Revascularization of multiple coronary arteries when the culprit artery cannot be clearly determined 	A ₍₉₎
11. <ul style="list-style-type: none"> • Patients with acute myocardial infarction (STEMI or NSTEMI) • Evidence of cardiogenic shock • Revascularization of 1 or more coronary arteries 	A ₍₈₎

*Subscripted numbers are a reflection of the continuum as per the appropriateness criteria methodology and should not be interpreted as "degrees of appropriateness or inappropriateness."

Patel et al, Catheter Cardiovasc Interv. 2009 Feb 15;73(3):E1-24

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Appropriateness Criteria for PCI

Table 2. Patients Without Prior Bypass Surgery

Indication	Appropriateness Score (1-3)		
	CCS Angina Class		
	Asymptomatic	I or II	III or IV
12. • One- or 2-vessel CAD without involvement of proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	1 _{AS} ^a	1 _{AS}	2 _{AS}
13. • One- or 3-vessel CAD without involvement of proximal LAD • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	1 _{AS}	2 _{AS}	3 _{AS}
14. • One- or 2-vessel CAD without involvement of proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	1 _{AS}	2 _{AS}	2 _{AS}
15. • One- or 3-vessel CAD without involvement of proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
16. • One- or 2-vessel CAD without involvement of proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
17. • One- or 3-vessel CAD without involvement of proximal LAD • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
18. • One- or 2-vessel CAD without involvement of proximal LAD • No noninvasive testing performed	2	2 _{AS}	3 _{AS}
19. • One- or 3-vessel CAD with borderline stenosis "50% to 50%" • No noninvasive testing performed • No further invasive evaluation performed (i.e., FFR, IVUS)	2	2 _{AS}	2 _{AS}
20. • One- or 3-vessel CAD with borderline stenosis "50% to 50%" • No noninvasive testing performed or equivocal test results (e.g., FFR or IVUS findings do not meet criteria for significant stenosis) • CCS less than 0.75 and/or IVUS with significant reduction in cross-sectional area	1 _{AS}	2 _{AS}	3 _{AS}
21. • One- or 2-vessel CAD with borderline stenosis "50% to 50%" • No noninvasive testing performed or equivocal test results (e.g., FFR or IVUS findings do not meet criteria for significant stenosis)	1 _{AS}	1 _{AS}	1 _{AS}
22. • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	1 _{AS}	1 _{AS}	1 _{AS}
23. • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	1 _{AS}	2 _{AS}	2 _{AS}
24. • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	1 _{AS}	2 _{AS}	2 _{AS}
25. • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	2 _{AS}	2 _{AS}	2 _{AS}
26. • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
27. • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
28. • One-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	2 _{AS}	2 _{AS}	3 _{AS}
29. • One-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}

Table 2. Continued

Indication	Appropriateness Score (1-3)		
	CCS Angina Class		
	Asymptomatic	I or II	III or IV
30. • One-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	2 _{AS}	2 _{AS}	3 _{AS}
31. • One-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving maximal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
32. • One-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
33. • One-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving maximal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
34. • Two-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	2 _{AS}	2 _{AS}	3 _{AS}
35. • Two-vessel CAD involving the proximal LAD • Low-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
36. • Two-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
37. • Two-vessel CAD involving the proximal LAD • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
38. • Two-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
39. • Two-vessel CAD involving the proximal LAD • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
40. • Three-vessel CAD (no left main) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving no or minimal anti-ischemic medical therapy	2 _{AS}	2 _{AS}	3 _{AS}
41. • Three-vessel CAD (no left main) • Low-risk findings on noninvasive testing including normal LV systolic function • Receiving a course of maximal anti-ischemic medical therapy	2 _{AS}	3 _{AS}	3 _{AS}
42. • Three-vessel CAD (no left main) • Intermediate-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
43. • Three-vessel CAD (no left main) • Intermediate-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
44. • Three-vessel CAD (no left main) • High-risk findings on noninvasive testing • Receiving no or minimal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
45. • Three-vessel CAD (no left main) • High-risk findings on noninvasive testing • Receiving a course of maximal anti-ischemic medical therapy	3 _{AS}	3 _{AS}	3 _{AS}
46. • Three-vessel CAD (no left main) • Abnormal LV systolic function	3 _{AS}	3 _{AS}	3 _{AS}
47. • Left main stenosis	3 _{AS}	3 _{AS}	3 _{AS}

^aUnstented stents are available for the treatment of the stenosis and should be implanted as "degrees of appropriateness in appropriateness." (Indicates that the stent given the findings of the stenosis is not the best stent for the patient and should not be performed.)

Appropriateness Criteria for PCI

Table 3. Patients With Prior Bypass Surgery (Without Acute Coronary Syndromes)

Indication		Appropriateness Score (1–9)		
		CCS Angina Class		
		Asymptomatic	I or II	III or IV
48.	<ul style="list-style-type: none"> One or more stenoses in saphenous vein graft(s) Low-risk findings on noninvasive testing including normal LV systolic function Receiving no or minimal anti-ischemic medical therapy 	I ₍₂₎	U ₍₄₎	U ₍₆₎
49.	<ul style="list-style-type: none"> One or more stenoses in saphenous vein graft(s) Low-risk findings on noninvasive testing including normal LV systolic function Receiving a course of maximal anti-ischemic medical therapy 	U ₍₄₎	U ₍₆₎	A ₍₇₎
50.	<ul style="list-style-type: none"> One or more stenoses in saphenous vein graft(s) Intermediate-risk findings on noninvasive testing Receiving no or minimal anti-ischemic medical therapy 	U ₍₄₎	U ₍₆₎	A ₍₇₎
51.	<ul style="list-style-type: none"> One or more stenoses in saphenous vein graft(s) Intermediate-risk findings on noninvasive testing Receiving a course of maximal anti-ischemic medical therapy 	U ₍₄₎	A ₍₇₎	A ₍₈₎
52.	<ul style="list-style-type: none"> One or more stenoses in saphenous vein graft(s) High-risk findings on noninvasive testing Receiving no or minimal anti-ischemic medical therapy 	U ₍₆₎	A ₍₇₎	A ₍₇₎
53.	<ul style="list-style-type: none"> One or more stenoses in saphenous vein graft(s) High-risk findings on noninvasive testing Receiving a course of maximal anti-ischemic medical therapy 	A ₍₇₎	A ₍₈₎	A ₍₉₎
54.	<ul style="list-style-type: none"> One or more lesions in native coronary arteries without bypass grafts All bypass grafts patent and without significant disease Low-risk findings on noninvasive testing including normal LV systolic function Receiving no or minimal anti-ischemic medical therapy 	†	I ₍₂₎	U ₍₆₎
55.	<ul style="list-style-type: none"> One or more lesions in native coronary arteries without bypass grafts All bypass grafts patent and without significant disease Low-risk findings on noninvasive testing including normal LV systolic function Receiving a course of maximal anti-ischemic medical therapy 	I ₍₂₎	U ₍₅₎	A ₍₇₎
56.	<ul style="list-style-type: none"> One or more lesions in native coronary arteries without bypass grafts All bypass grafts patent and without significant disease Intermediate-risk findings on noninvasive testing Receiving no or minimal anti-ischemic medical therapy 	I ₍₂₎	U ₍₅₎	A ₍₇₎
57.	<ul style="list-style-type: none"> One or more lesions in native coronary arteries without bypass grafts All bypass grafts patent and without significant disease Intermediate-risk findings on noninvasive testing Receiving a course of maximal anti-ischemic medical therapy 	U ₍₄₎	U ₍₆₎	A ₍₈₎
58.	<ul style="list-style-type: none"> One or more lesions in native coronary arteries without bypass grafts All bypass grafts patent and without significant disease High-risk findings on noninvasive testing Receiving no or minimal anti-ischemic medical therapy 	U ₍₆₎	A ₍₇₎	A ₍₈₎
59.	<ul style="list-style-type: none"> One or more lesions in native coronary arteries without bypass grafts All bypass grafts patent and without significant disease High-risk finding on noninvasive testing Receiving a course of maximal anti-ischemic medical therapy 	U ₍₅₎	A ₍₈₎	A ₍₉₎

*Subscripted numbers are a reflection of the continuum as per the appropriateness criteria methodology and should not be interpreted as "degrees of appropriateness or inappropriateness." †Indicates that the writing group felt the likelihood of the clinical scenario was so low that rating should not be performed.